Docket No.: 223002107000
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Paul A. BARSANTI, et al.	Confirmation No.: 8570
Application No.: 10/748,071	Art Unit: 1648
Filed: December 29, 2003	Examiner: S. Snyder
For: THIOSEMICARBAZONES AS ANTI-VIRALS AND IMMUNOPOTENTIATORS	

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE UNDER 37 CFR §1.104(E)

MS Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

Applicants have received the Examiner's Statement of Reasons for Allowance with the December 9, 2008 Notices of Allowance and Allowability regarding the above-identified application. Entry of the Statement into record should not be construed as any agreement with or acquiescence in the reasons stated by the Examiner. Each of the claims stands on its own merits and is patentable because of the combination it recites and not because of the presence or absence of any one particular element.

The Examiner's amendment removed the phrase 'in an amount effective to potentiate a cell-mediated immune response to the vaccine'. The Examiner indicated that the claims as amended are patentable; Applicants agree and appreciate the Examiner's recommendation. However, the Examiner identified certain pragmatic challenges associated with testing to determine the 'amount'

needed to enhance a cell-mediated immune response (CMI response), including limitations on access to test animals, or ethical limitations on large scale testing in humans. Applicants believe the test animal availability comments are misleading, since animals for vaccine testing are routinely available both here and abroad. Animal testing even if not absolutely predictive is well established as a step toward human testing, and such testing in animals is routinely done for optimizing vaccine formulations. Applicants also believe the comments regarding testing in unvaccinated humans overlook alternatives, e.g., even in a vaccinated subject one could determine how much compound to use in combination with a different antigen, or how much was needed to provide a boosting effect on the cell-mediated immune response levels to the same antigen that the vaccinee has been exposed to before. Test formulations would not need to go into humans on a large scale (animal testing provides an effective screening process), and they would not need to be used as replacements for effective ones in 'large scale' testing. The person of ordinary skill has ways to establish the effective amount of the compound for enhancing a CMI response.

Applicants submit this Comments on Statement of Reasons for Allowance with Applicants' payment of the Issue Fee.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 223002107000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 5, 2009

Respectfully submitted,

Electronic signature: / Michael G. Smith /
Michael G. Smith
Registration No.:44,422
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 720-5113